

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/557,577 04/21/00 KAYYEM

J A-63761-5/RF

EXAMINER

HM12/0605

ROBIN M SILVA ESQ
FLEHR HOHBACH TEST ALBRITTON & HERBERT L
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

MARSCHEL, A

ART UNIT

PAPER NUMBER

5

1631
DATE MAILED:

06/05/01

BEST AVAILABLE COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/557,577	Applicant(s) Kayyem et al.
Examiner Ardin Marschel	Art Unit 1631



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-59 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 1-59 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing ~~submitted~~ filed on 4/21/00 is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, the specification on page 126, line 1, and elsewhere. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, and a statement under 37 CFR § 1.821(f). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-21, 34, 35, 45, and 46; drawn to a composition containing an electrode, at least one nucleoside, and a conductive oligomer; and methods of making same; classified in Class 536, subclass 22.1.

II. Claims 22-27, drawn to electrode based methods of detecting a target nucleic acid sequence; classified in Class 435, subclass 6.

III. Claims 28-32, drawn to methods for attaching a conductive oligomer to a gold electrode; classified in Class 422, subclass 50.

IV. Claim 33, drawn to a conductive oligomer; classified in Class 552, subclass 208.

V. Claims 36-44, drawn to a composition containing a nucleoside and a conductive oligomer; classified in Class 536, subclass 22.1.

VI. Claims 47-59; drawn to a peptide nucleic acid attached to a monomeric unit; classified in Class 530, subclass 300. If this group is elected then the below summarized specie election requirement is also required.

ADDITIONAL SPECIE ELECTION REGARDING GROUP VI ONLY:

This application contains claims directed to the following patentably distinct species of the claimed invention:

SPECIE VIA: peptide nucleic acids without an attached electrode

SPECIE VIB: peptide nucleic acids with an attached electrode

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 47-51 and 53-59 are generic in Group VI. The presence or absence of an electrode on the peptide nucleic acid are distinct species as they direct any usage to electrode assay methods versus solution assays or other uses which do not require an electrode for measurement.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic

is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The invention Groups I, II, III, and VI(electrode specie) are distinct from Groups IV, V, and VI(non-electrode specie) due to the difference in electrode presence and usage. The electrode presence constrains the use to a solid phase method with electrical activation or sensing which is a very special type of assay which is not commonly described with liquid phase assays or other assays which utilize signaling of various types such as dyes etc. Thus, the search for each of these sets of invention Groups, performed together is an undue search burden as assays of any special type is a large search subject matter area.

Inventions of Groups I and VI(electrode specie) and Group II are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the products may be utilized in the distinct method of treatment utilizing an electrical activation via the electrode.

The inventions of Groups I and VI(electrode specie) are distinct as being directed to different chemical types which function under different conditions and are prepared differently.

Inventions of Group III and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the linkage of a conductive oligomer may occur via a wide variety of linkers other than the ethyl pyridine/sulfur type of Group III.

The inventions of Groups IV, V, and VI(non-electrode specie) are each directed to different oligomer types which may or may not require any of the other types for their usage and are thus distinct. For example, a conductive oligomer of Group IV may be utilized in a variety of chemical reactions, such as with antibodies or enzymes, without a nucleic acid or peptide nucleic acid reagent component.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 31, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER